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ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,912	POLLI ET AL.	
	Examiner	Art Unit	
	MICHAEL FUELLING	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/28/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Appendix*.

DETAILED ACTION

This is a non-final office action for Application Number 10/572,912 filed 3/21/2006.

Claims 1-32 currently are pending.

Claims 1-10 have been amended.

Claims 11-32 have been cancelled.

Claims 1-10 have been examined.

Notice to Applicant

Applicant's amendment technically was non-compliant with 37 CFR 1.121 as it identified claim 33 as being cancelled and there was not a claim 33. The examiner has refrained from merely issuing a notice of non-compliance and has examined the amended claims on their merits. Future replies must comply with 37 CFR 1.121.

Election/Restrictions

Applicant's amendment of 12/14/2010 without traverse in response to the 9/21/2010 restriction requirement is acknowledged.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 12/28/2010 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement was considered by the examiner.

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

The drawings could be objected to because they do not include reference numbers, however, such an objection will be held in abeyance.

Specification

A significant use of third party trademarks has been noted in this application. They should be capitalized whenever used and accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

As with the drawings, the disclosure also could be further is objected to because it does not use reference numbers when referring to parts of the drawings.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim contains improper Markush grouping. The species of the Markush group do not share a single structural similarity. Claims 5, 7 and 10, which are dependent on claim 4, further limit the inactive ingredient to i) a binder; ii) a filler or iii) a disintegrant. The examiner would accept this as a proper group as an excipient starch might serve as a binder, a filler or a disintegrant, depending on the processing conditions.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 1-10 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Based upon consideration of all of the relevant factors with respect to the claim as a whole, claim 1 is held to claim an abstract idea, and is/are therefore rejected as ineligible subject matter under 35 U.S.C. 101. The rationale for this finding is explained below: no recitation of a machine or transformation (express or inherent). Varying an amount is not a transformation, and the claim makes clear no transformation has occurred because the varied component is inactive. Further, the product might merely be a data table and the components could be items on it.

Dependent claim 2 when analyzed as a whole is held to be patent ineligible under 35 U.S.C. 101 because the additional recited limitation(s) fail(s) to establish that the claim(s) is/are not directed to an abstract idea, as detailed below: no recitation of a machine or transformation (express or inherent). Varying an amount is not a transformation, and the claim makes clear no transformation has occurred because the varied component is inactive. Further, the product might merely be a data table and the components could be items on it.

Based upon consideration of all of the relevant factors with respect to the claim as a whole, claim 3 is held to claim an abstract idea, and is/are therefore rejected as ineligible subject matter under 35 U.S.C. 101. The rationale for this finding is explained below: no

recitation of a machine or transformation (express or inherent). Varying an amount is not a transformation, and the claim makes clear no transformation has occurred because the varied component is inactive. Further, the product might merely be a data table and the components could be items on it.

Dependent claims 4-10 when analyzed as a whole is held to be patent ineligible under 35 U.S.C. 101 because the additional recited limitation(s) fail(s) to establish that the claim(s) is/are not directed to an abstract idea, as detailed below: no recitation of a machine or transformation (express or inherent). Varying an amount is not a transformation, and the claims make clear no transformation has occurred because the varied component is inactive. Further, the product might merely be a data table and the components could be items on it.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Julia et al., US Patent No. 6,907,351 (Julia) in view of admitted prior art / Rzasa et al., US Patent No. 6,771,369 (Rzasa).

As per claim 1:

Claim 1 recites "the varied amount" and it is unclear if this is the same as the "intentionally" varied amount. It is being interpreted that they are the same component.

The claim also was amended to recite "thereby intentionally labeling the pharmaceutical product". The specification describes intentionally varying amounts, however, the specification does not describe how this results in the act of "intentionally labeling". Moreover, the written description and originally filed claims are devoid such phrase. It is being interpreted that the product signature / NIR spectra resulting from intentionally varying the amounts is the intentional label.

Julia discloses:

intentionally varying an amount (Abstract "predicting content level of components in materials") of at least one of the one or more inactive ingredients (C4, L28 "inactive ingredients) in a pharmaceutical product (C4, L10-15 pharmaceuticals) to generate a product signature / NIR spectra / label (C5, L51 "spectra") of the pharmaceutical product having the varied amount of the at least one of the one or more inactive ingredients (Abstract using near infrared radiation (NIR) **120**).

To the extent it can be shown that Julia does not expressly disclose the term "signature", applicant's use of the term is a nonfunctional description of the data. Nonfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. *In re Ngai*, 367 F.3d 1336, 1339 (Fed. Cir. 2004). *Cf. In re Gulack*, 703 F.2d 1381, 1385 (Fed. Cir. 1983) (when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability).

Moreover, applicant's admitted prior art in its background section references Rzasa. Rzasa evidences that the term signature is a term of art for identifying a pharmaceutical by the quantity of an ingredient (C2, L64 "signature").

As per claim 2:

Claim 1 recites "intentionally labeling" and this dependent claim recites "a label" (emphasis added). It is being interpreted that these are the same label.

Julia further discloses NIR spectral data / labels (Abstract using near infrared radiation (NIR); C5, L51 "spectra" and **120**).

To the extent it can be shown that Julia does not expressly disclose the term "signature", applicant's use of the term is a nonfunctional description of the data. Nonfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. *In re Ngai*, 367 F.3d 1336, 1339 (Fed. Cir. 2004). *Cf. In re Gulack*, 703 F.2d 1381, 1385 (Fed. Cir. 1983) (when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability).

Moreover, applicant's admitted prior art in its background section references Rzasa. Rzasa evidences that the term signature is a term of art for identifying a pharmaceutical by the quantity of an ingredient (C2, L64 "signature").

4. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over an embodiment Julia in view of the background of Julia.

As per claim 3, Julia discloses:

- intentionally varying an amount of at least one of the one or more inactive ingredients (C4, L28 "inactive ingredients) among different pharmaceutical products produced (Abstract "predicting content level of components in materials" and C4, L10-15 pharmaceuticals),

-- wherein variation in the amount of, at least one of the one or more inactive ingredients in a product results in an NIR spectrum for the product that detectably differs from an NIR spectrum for a different product among the plurality of products (Abstract using infrared **120**).

To the extent that it can be shown that the disclosed embodiment(s) of Julia are being applied to continuous manufacturing, rather than batch production, such that Julia might not appear to expressly disclose the feature of:

-- thereby identifying the source of the lot / batch / product of the pharmaceutical product from among a plurality of lots / batches / products of the pharmaceutical product.

Julia's background teaches that batch production is an old and well known product manufacturing technique (C1, L44 batches).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Julia's NIR product identification method to apply it to distinguishing between different batches of pharmaceutical products, and the results would have been predictable, because it is the application of a known technique to a known method.

One would have been motivated to make the combination because it would help to improve monitoring the contents of the products.

5. Claims 4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over an embodiment Julia in view of the background of Julia, as applied to claim 3 above, in further view of US Food and Drug Administration (FDA), Scale-up and Post-Approval Changes Guidance for Immediate Release Products, November 30, 1995 (SUPAC-IR).

As per claim 4, Julia discloses or teaches all of the limitations of claim 3 as detailed above.

Julia, however, might not appear to expressly disclose varying the amounts of filler, binder or disintegrant inactive ingredients in pharmaceutical products.

SUPAC-IR teaches that it is old and well known to vary the amounts of filler, binder and/or disintegrant inactive ingredients in pharmaceutical products as evidenced by the portion of its questions & answers copied below.

4. Q: How does one apply SUPAC-IR to multifunctional excipients, e.g., starch?

A: SUPAC-IR composition changes are based on being able to define the use or action of the particular excipient in the product. This rationale should be included by the applicants as part of their original applications. Not all multifunctional excipients are listed in the guidance. However, if an excipient was utilized to provide multiple functions such as pregelatinized starch as a filler, starch as a disintegrant, starch paste as a binder, then the most conservative recommended change should be followed (e.g., for an excipient that is a filler, disintegrant and binder, the recommended limit for a Level 2 change is 0.5 percent, see page 7, SUPAC-IR).

It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the invention of Julia to include varying the amounts of filler, binder and/or disintegrant inactive ingredients in pharmaceutical products, because it is the application of a known technique to a known method, and the results would have predictable to one of ordinary skill in the art.

One would have been motivated to apply the technique to achieve a desired property for the pharmaceutical product and/or reduce the cost of the pharmaceutical product while complying with the law.

As per claims 5 and 6, Julia and SUPAC-IR disclose or teach all of the limitations of claim 4 as detailed above.

Julia, however, might not appear to expressly disclose varying the amounts of filler inactive ingredients in pharmaceutical products by the claimed ranges.

It is the examiner's opinion that the claimed ranges are fairly suggested by SUPAC-IR as evidenced by the portion of its questions & answers copied below.

9. Q: When microcrystalline cellulose is increased by 5%, the tablet weight increases. Can this still be a level 1 change?

A: After the SUPAC-IR change, if the new target weight is still within the range in the approved original application, it is a level 1 change. Otherwise, it is a Level 2 or 3 change, both of which are to be submitted as a prior approval supplement.

It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the invention of Julia to include varying the amounts of filler inactive ingredients in pharmaceutical products by the claimed ranges, because it is the application of a known technique to a known method, and the results would have predictable to one of ordinary skill in the art.

One would have been motivated to apply the technique to achieve a desired property for the pharmaceutical product and/or reduce the cost of the pharmaceutical product while complying with the law.

As per claims 7-10, Julia and SUPAC-IR disclose or teach all of the limitations of claim 4 as detailed above.

Julia, however, might not appear to expressly disclose varying the amounts of binder or disintegrant inactive ingredients in pharmaceutical products by the claimed ranges.

It is the examiner's opinion that the claimed ranges are fairly suggested by SUPAC-IR as evidenced by certain portions of its questions & answers copied below.

4. Q: How does one apply SUPAC-IR to multifunctional excipients, e.g., starch?

A: SUPAC-IR composition changes are based on being able to define the use or action of the particular excipient in the product. This rationale should be included by the applicants as part of their original applications. Not all multifunctional excipients are listed in the guidance. However, if an excipient was utilized to provide multiple functions such as pregelatinized starch as a filler, starch as a disintegrant, starch paste as a binder, then the most conservative recommended

change should be followed (e.g., for an excipient that is a filler, disintegrant and binder, the recommended limit for a Level 2 change is 0.5 percent, see page 7, SUPAC-IR).

It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the invention of Julia to include varying the amounts of binder or disintegrant inactive ingredients in pharmaceutical products by the claimed ranges, because it is the application of a known technique to a known method, and the results would have predictable to one of ordinary skill in the art.

One would have been motivated to apply the technique to achieve a desired property for the pharmaceutical product and/or reduce the cost of the pharmaceutical product while complying with the law.

Rule 37 CFR 1.105

A page from infratrac.com is being attached as an appendix to this Office Action. The website represents that the InfraTrac venture has rights to certain granted patents, which may have priority date(s) earlier than this application. While it appears that there is some relationship between the inventor(s) and InfraTrac, the examiner is refraining from making a request for information.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Buchanan teaches that the concept of intentionally varying inactive ingredients in pharmaceuticals to uniquely identify them by their chemical formulation using NIR [0075-0076].

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL FUELLING whose telephone number is (571)270-1367. The examiner can normally be reached on Monday - Friday, 8:30 am - 5 pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Morgan can be reached on (571)272-6773. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. F./
Examiner, Art Unit 3626

/Robert Morgan/
Supervisory Patent Examiner, Art Unit 3626